Uniform Formulary TRICARE Retail Network Rebates Quotes and Uniform Formulary Voluntary Agreement for TRICARE Retail Rebates (UF-VARR)

CAVEAT: The Uniform Formulary Voluntary Agreement for TRICARE Retail Network Rebates (UF-VARR) outlined in this rebate quote and Agreement is separate from and exclusive of any TRICARE Retail Network Pharmacy refunds that may be available under Section 603 of the Veterans Health Care Act of 1992 (VHCA) since October 1, 2004. Parties to any UF-VARR acknowledge that the Department of Veterans Affairs determination, authorizing TRICARE Retail Network Pharmacy program refunds under VHCA, is the subject of litigation in federal court. The parties agree that participation in a UF-VARR does not constitute any abandonment or relinquishment by either party of any right or position relative to that litigation, and the existence of any UF-VARR may not be used by either party as support for its position or to refute the position taken by the other party. Further, Department of Defense (DoD) acceptance of any UF-VARR rebate quote or rebate payment shall not constitute a waiver by the DoD of its position that it is entitled to enforce and collect any additional refund available for the UF-VARR pharmaceutical agents listed in Table 1 hereof that may have been available to the Department under the VHCA for the TRICARE Retail Network Pharmacy refund program; provided, that any rebates collected under this Agreement will be considered partial payment toward any amount outstanding from the available refund that the DoD contends is due under VHCA. In addition, the parties acknowledge that the General Services Administration has published a proposed rule to amend the General Services Acquisition Regulation (GSAR) to add a new clause authorizing Federal Agency Retail Network Pharmacy (including TRICARE) refunds based on Federal Supply Schedule (FSS) pharmaceutical contract prices. Therefore, the parties further agree that participation in a UF-VARR does not constitute any abandonment or relinquishment by either party of any right or position relative to GSA publication and/or implementation of such a final rule. Further, DoD acceptance of any UF-VARR rebate quote or rebate payment shall not constitute a waiver by the DoD of its position that it is entitled to enforce and collect any additional refund available for the UF-VARR pharmaceutical agents listed in Table 1 hereof that may be available to the Department following implementation of a final GSA rule authorizing refunds based on FSS pharmaceutical prices for the TRICARE Retail Network Pharmacy program. Unless and until a final rule is published and becomes effective to bring TRICARE Retail Network Pharmacy transactions under the terms of the Company's FSS contract, such transactions will not be considered FSS sales and will not be subject to collection of any Industrial Funding Fee (IFF).

1. REBATE QUOTE FOR INCLUSION ON UNIFORM FORMULARY: By submitting this Uniform Formulary Voluntary Agreement for TRICARE Retail Rebates (UF-VARR) quote, the pharmaceutical manufacturer listed in Paragraph 13, The Company, below (henceforth Company) agrees to provide rebates to the Government based on the accrued utilization of and the rebate stated for the pharmaceutical agent(s) listed in the attached Table 1. The accrued utilization will be based on the listed pharmaceutical agents that are dispensed to DoD beneficiaries by TRICARE network pharmacies under the DoD pharmacy benefits management contract associated with the TRICARE Retail Pharmacy program. The rebate quote(s) for the

pharmaceutical agent(s) listed in Table 1 is (are) contingent upon such pharmaceutical agent(s) being included on the Department of Defense (DoD) Uniform Formulary (UF) in not worse than the formulary (2nd) cost share tier The DoD Pharmacy and Therapeutics (P&T) Committee will consider the rebate quote for the pharmaceutical agent(s) listed in Table 1 as part of its evaluation of the relative cost effectiveness of pharmaceutical agents in recommending the selection of agents for the UF in such therapeutic class, and the classification of a pharmaceutical agent in the generic (1s`), formulary (2nd), or non-formulary (3rd) cost share tier. If the P&T Committee determines that a pharmaceutical agent should be recommended for inclusion on the UF, the P&T Committee will determine whether the pharmaceutical agent should be placed in the generic or formulary cost share tier in accordance with 32 C.F.R. 199.21(j). If the Director, TRICARE Management Activity (TMA), makes a final decision to accept the recommendations of the DoD P&T Committee relevant to the pharmaceutical agent(s) contained in the Company's rebate quote and places the pharmaceutical agent(s) on the Uniform Formulary in not worse than the formulary (2nd) cost share tier, the TMA Chief, Pharmaceutical Operations, on behalf of the Department of Defense, will establish a UF-VARR by completing Paragraph 14, UF-VARR Execution, below.

2. SCOPE: Company's quoted rebate along with quarterly TRICARE Retail Network utilization for quoted NDCs will be used to calculate the amount due under this Agreement and the amount to be paid to the Government as outlined in this Agreement.

3. EFFECTIVE DATE and PERIOD OF RESULTING PRICING AGREEMENT: The Agreement effective date shall be the date that the Director, TMA, makes the final decision regarding placement of the pharmaceutical agent(s) on the UF. Rebate accrual and invoicing will be calculated in accordance with Paragraph 8. The Agreement will continue until the effective date of any change in the classification of the pharmaceutical agent(s) contained in the Agreement as UF agent(s), or is otherwise terminated in accordance with Paragraph 10, Termination, below.

4. ELIGIBLE TRANSACTIONS: The rebate will apply to all prescription transactions where a TRICARE Retail Network Pharmacy dispenses a pharmaceutical agent listed in Table 1 to a DoD beneficiary in accordance with terms of the DoD pharmacy benefits management contract associated with the TRICARE Retail Pharmacy program. Company shall not be required to pay a rebate under this Agreement with respect to utilization of a pharmaceutical agent if such agent was dispensed at a Military Treatment Facility (MTF); TRICARE Mail Order Pharmacy (TMOP); or non-network retail pharmacies. Additionally, Company shall not be required to pay a rebate under this Agreement for retail dispensings submitted for reimbursement by DoD beneficiaries (paper/Direct Member Reimbursement (DMR) claims); retail dispensings submitted for reimbursement by state Medicaid agencies; retail dispensings submitted for reimbursement by commercial payers (e.g., Coordination of Benefits (COB) claims); retail dispensings submitted for reimbursement by aggregators/clearinghouses; compounded prescriptions; or repackaged products

5. EXTENT OF GOVERNMENT OBLIGATION: The placement of the listed pharmaceutical agent(s) in the UF in not worse than the formulary (2nd) cost share tier in accordance with the final decision of the Director, TMA is a condition of receiving rebates

under this Agreement. This Agreement imposes no obligation on the DoD to purchase any product.

6. **FINAL APPROVAL BY GOVERNMENT:** In submitting this UF-VARR rebate quote for the pharmaceutical agent(s) listed in Table 1 hereto, the Company understands that the DoD P&T Committee will consider the quoted rebate(s) in determining the cost of such pharmaceutical agent(s) to the government as part of its cost effectiveness evaluation of such pharmaceutical agent. The incorporation of a rebate quotation into a DoD executed UF-VARR is contingent upon final decision of the Director, TMA, approving the recommendations of the DoD P&T Committee.

7. REBATE and NATIONAL DRUG CODE (NDC) CHANGES:

(a) Company agrees to hold open its UF-VARR rebate quote for 180 days.

(b) Rebate quotes will be submitted as a percentage (expressed to two decimal places XX.XX%) of Wholesale Acquisition Cost (WAC) for each NDC-11. WAC is the U.S. Dollar proprietary price set by each pharmaceutical company using its own formula. During the time period that the UF-VARR is in effect, Company may offer larger rebates at any time. After UF decisions for pharmaceutical agents included in this Agreement are made and while this Agreement is in effect, Company may submit supplementary performance-based agreements for increased rebates for consideration by the DoD but shall be under no obligation to do so.

(c) In the event that Company ceases manufacturing or selling any NDC of any pharmaceutical agents listed in this UF-VARR agreement, such NDC shall be deemed deleted from this UF-VARR effective 120 days after notice is given by Company to the Government. If any NDC-11 is deleted or for any reason no longer available for purchase, Company shall work with the Government to identify new or reasonably equivalent product listings (NDCs), in order that the Government will continue to receive rebates commensurate with UF placement for these pharmaceutical agents. Generally, the Company may calculate an equivalent rebate at the product strength level.

8. UTILIZATION ACCRUAL AND INVOICING: For purpose of calculating the rebate, the accrual of TRICARE Retail Network utilization will begin on the date that the UF status becomes effective in the TRICARE Retail Pharmacy Network. Rebates shall be calculated based on the WAC in effect on the date that the UF status becomes effective in the TRICARE Retail Pharmacy Network; provided that if WAC changes during a calendar quarter, rebates shall be payable based on the average WAC for such calendar quarter, calculated on a day-weighted basis. The Government shall provide utilization data to Company in accordance with the "Process and Procedures Guide for Manufacturer Refunds" found at http://www.tricare.osd.mil/pharm_mfg/downloads/ProcessandProceduresGuideJune05.pdf..

(a) The billing cycle will be quarterly with billing periods of January through March, April through June, July through September, and October through December. Invoices will be distributed by DoD on or about the 15th day of the month following the preceding billing period with payment due 70 days from the invoice date. A request for extension of the invoice due date

must be submitted to the appropriate DoD office no later than 14 calendar days prior to the invoice due date. The manufacturer will remit any rebate due the government based upon the data provided by the DoD with which the manufacturer disagrees, except in the following circumstances:

- The disputed NDC(s) has been divested.
- The claim has been included in another PBM's submission.

Although Company is permitted to withhold payment in the above two situations, Company should include an itemized listing of these claims and the specific reason for payment withhold along with their quarterly reconciliation document. Failure to pay in full in all other circumstances by the designated invoice due date without an approved extension may result in the termination of this UF-VARR and reconsideration by the DoD P&T Committee of the listed pharmaceutical agents' placement on the UF, in addition to any other remedies available to DoD.

(b) The DoD will provide billing information for the payment and reconciliation material due by Company, and obtain invoicing information for the Company's agent listed in Paragraph 13, The Company, below. Invoices will note the billing period, and provide a summary of accrued utilization by product listing (NDC-11) for that billing period by unit (tablet, capsule, inhaler, etc.) and the percent rebate in this UF-VARR. Company will submit reconciliation material with payment to include the current WAC (as of invoice date) for each invoiced product listing and the dollar total of the rebate by product listing.

(c) Company may request a report of the billing period's accrued utilization by transaction from DoD.

9. RESOLUTION OF DISAGREEMENTS CONCERNING DATA USED TO DETERMINE REFUNDS.

(a) If Company disagrees with Government's data in the summary of accrued utilization or the billing invoice under Paragraph 8, Utilization Accrual and Invoicing, above, the Company shall provide prompt written notice to the Government. Such notice shall be received by the Government no later than 10 business days after the Company's discovery of the alleged error, but in no event later than one year after the date of the quarterly report containing the alleged erroneous data. The notice shall include specific identification of the alleged error(s) and the specific reason(s) the Company believes the data to be in error, along with all available documentation that supports the Company's allegation(s).

(b) The Government will initiate a prompt review of the data following receipt of the notice and documentation provided by the Company. The parties agree to use their best good faith efforts to resolve any disagreement within 60 days of the Government's receipt of the Company's written notice. During this period, the Company shall proceed diligently with performance of this agreement, and will exhaust administrative remedies under this clause prior to pursuing any other course of relief or remedy. Performance includes remittance of any rebate due the Government based upon the data provided by the Government with which the Company

disagrees, excluding the two exceptions referenced in Paragraph 8(a). If the written notice of disagreement is resolved in favor of the Company, the Government shall reimburse the Company the amount of remitted rebate attributed to the error and simple interest on the reimbursed amount at the rate identical to such rate established in accordance with the Contract Disputes Act of 1978, as amended (41 U.S.C. §§ 601-613), from the date of receipt of the Company's remittance of the refund in disagreement. If the written notice of disagreement involving any authorized Company withhold of payments under Paragraph 8(a) above is resolved in favor of the Government, the Company shall pay the Government the withheld rebate attributed to the error and simple interest at a rate identical to such rate established in accordance with the Contract Disputes Act of 1978, as amended (41 U.S.C. §§ 601-613), from the due date of the invoice on which the rebate was withheld.

(c) If the Government and Company cannot resolve the disagreement within 60 days following receipt of the Company's written notice (and any time extensions mutually agreed to by the parties), the Company shall be considered to have exhausted administrative remedies under this UF-VARR and is free to pursue any other available course of relief or remedy.

10. TERMINATION: Except as provided in Paragraph 7(a) of this Agreement, either party may terminate this UF-VARR by providing written notice to the other. Such notice shall be effective one hundred twenty (120) days following receipt of written notice of termination by the other party.

11. GENERAL PROVISIONS: The Company is not required to have an existing FSS Contract for any pharmaceutical agent(s) quoted in this UF-VARR.

12. **UF-VARR SUBMISSIONS:** Send all submissions to:

Chief, Pharmaceutical Operations
ATTN: UF VARR
TRICARE Management Activity
Skyline Five, Suite 810
5111 Leesburg Pike
Falls Church, VA 22041-3206

13. THE **COMPANY:** The Company point of contact for the administration and management of this agreement is:

Name: _____
Title: _____
Address _____
_____
Phone: _____ FAX: _____
Email: _____

FOR THE COMPANY

BY:*(signature)*_____ *DATE:* _____

Name _____

Title_____

[Name of COMPANY]

_____

14. UF-VARR EXECUTION: (To be completed by Chief, Pharmaceutical Operations) A Uniform Formulary Voluntary Agreement for TRICARE Retail Network Rebates (UF-VARR) is hereby established between the Company and the Department of Defense for the pharmaceutical agents and applicable rebates quoted in the attached Table based on the final decision of the Director, TMA, to include the pharmaceutical agents on the Uniform Formulary

BY: *(signature)*_____ _____

Name: _____ Date UF Decision

TMA Chief, Pharmaceutical Operations

Table 1. Uniform Formulary Rebate Quote

P&T Committee designated Therapeutic **Drug Class** quoted in this UF-VARR: _____ _____

The prices included in this table are contingent on the Condition Set #_____ outlined in Appendix A of this template and each specific Drug Class Review web page found linked to Drug Classes Under Review.

Pharmaceutical Agent					Wholesale Acquisition Cost (WAC) at time of submission. See para. 8 for the use of WAC during rebate processing		Rebate percentage if Included on UF (and classified as generic or formulary)	Resulting rebate at time of submission	
Drug Name	Dosage Strength	Dosage Form Unit	Package Size	NDC	$ Per Package	$ Per Dosage Form Unit	% of WAC	$ Per Package	$ Per Dosage Form Unit
(example)Gorillastatin	500 Mg	Tablet	100	12345678901	100.00	1.0000	25%	25.00	0.2500

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